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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Talarico *et al.*

Confirmation No.: 8297

Appl. No.: 09/934,300

Group Art Unit: 1645

Filed: 8/21/01

Examiner: S. Devi

METHODS FOR PURIFICATION OF AN ACTIVATED PEG SOLUTION  
AND FOR THE SYNTHESIS OF A MODIFIED HEMOGLOBIN SOLUTION

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

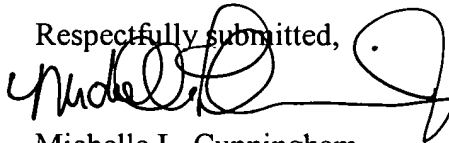
## SUPPLEMENTAL CITATION UNDER 37 C.F.R. § 1.97

Attached is a Supplemental Form PTO-1449 listing several documents that were first cited in the European Search Report for the corresponding European Application Number 02757260.1 not more than three months prior to the filing of this Statement. In this regard, Applicant notes that the European Search Report was not received by any individual designated by 37 CFR 1.56(c) more than thirty (30) days prior to the filing of this Information Disclosure Statement.

A copy of each document, including the Search Report, is enclosed. It is requested that the Examiner consider these documents and officially make them of record in accordance with the provisions of 37 C.F.R. § 1.97 and Section 609 of the MPEP. By submitting the listed documents, Applicant in no way makes any admission as to the prior art status of the listed documents, but is instead submitting the listed documents for the sake of full disclosure.

It is not believed that fees are due for the submission of this paper. However, in the event that that fees are required, authorization is given to charge our Deposit Account No. 16-0605.

Respectfully submitted,



Michelle L. Cunningham

Registration No. 51,072

## CERTIFICATE OF MAILING

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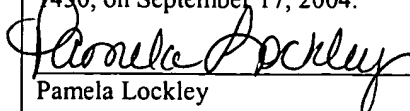
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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on September 17, 2004.

  
Pamela Lockley

Substitute for form 1449/PTO  
(Revised 04/2003)

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 1

## **Complete if Known**

Application Number 09/934,300  
Filing Date 8/21/01  
First Named Inventor T. Talarico  
Group Art Unit 1645  
Examiner Name S. Devi  
Attorney Docket Number 035780/233666

## **U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Document Number Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear
	15	US-5,234,903	08-10-1993	NHO <i>et al.</i>	

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No.	Foreign Patent Document Country Code - Number Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	English Language Translation Attached
	16	WO 02/44214 A1	06-06-2002	Apex Bioscience, Inc.		
	17	WO 90/15613	12-27-1990	Rorer Int'l, Inc.		

## **OTHER DOCUMENTS**

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	English Language Translation Attached
	18	MATSUMURA, S., "Large Scale Production and Characterization of Lyophilized Pyridoxalated Hemoglobin-Polyoxyethylene (PHP)," <i>Biomat., Art. Cells &amp; Immob. Biotech.</i> , 1992, Vol. 20(2-4), pp. 435-438.	
	19	TALARICO, T.L., "Comparability Analysis to Support a Manufacturing Site Change and Process Modifications for a Biopharmaceutical: A Regulatory Submission Case Study," <i>BioPharm</i> , 1999, Vol. 12(1), pp. 42-47.	

Examiner Signature

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RTA01/2162496v1

The PTO did not receive the following listed items(s) Cite # 16, 17, 18, 19